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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,949	12/03/2003	Andres Belalcazar	09531-157001 / Z04067	5410
26191	7590	03/31/2006		
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER DRYDEN, MATTHEW DUTTON	
			ART UNIT 3736	PAPER NUMBER
DATE MAILED: 03/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,949

Applicant(s)

BELALCAZAR ET AL.

Examiner

Matthew D. Dryden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/3/2003.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant claims that you can calculate an injected current by dividing a telemetered voltage by the telemetered current, this does not equate to a value for current but rather impedance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 28, 29, 32-35, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Prutchi (6370424).

Regarding claim 22, Prutchi discloses a monitor with synchronized bioimpedance sensing comprising:

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a receiver (see Column 7, lines 9-15) that receives information about an electrical current injected between first and second internal electrodes (see elements 27 and 31 in Figure 1) positioned such that a portion of the injected current flows through at least a portion of the region, the received information being telemetered from a device that injects the current, the device and the internal electrodes being implanted in the body (see Figure 1),

an interface (see Columns 8-9, lines 51-22) that receives a voltage signal detected by first and second external electrodes (elements 108c and 108d in Figure 3) attached to an external surface of the skin of the body, the detected voltage being induced by the injected current,

and a processing unit (around element 106 in Figure 3) that is capable of determining the fluid volume in the region by calculating a first impedance from the voltage signal and the received information about the injected current.

Regarding claim 28, the implantable cardiac device of Prutchi that applies a voltage between the first and second internal electrodes to accomplish the current injection (see Columns 7-8, lines 16-50).

Regarding claim 29, see Column 6, lines 55-63.

Regarding claim 32, the housing of pacemaker 10 serves as a second internal electrode (see Column 7, lines 16-30).

Regarding claim 33, see Column 7, lines 22-26, wherein the sensing circuits measure lead impedance of the first and second internal electrodes.

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Regarding claim 34, the received information would comprise a telemetered value of the voltage applied and a telemetered value of measured impedance (see Columns 8-9, lines 51-3).

Regarding claim 35, the processing unit of Prutchi is capable of calculating the injected current by dividing the telemetered voltage by the impedance value.

Regarding claim 41, (see Column 7, lines 9-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-12, 14-21, 23-25, 30, 31, 36-40, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Pitts-Crick et al (6595927). Prutchi discloses the claimed invention except for the calculated impedance being related to the volume of fluid in the region, specifically the lung. Prutchi discloses the steps of injecting an electrical current between first and second internal electrodes (see Column 6, lines 42-54, and Column 7, lines 1-55) and measuring a voltage between first and second external electrodes (see Column 9, lines 4-22). Pitts-Crick et al teaches it is known to take impedance measurements that are caused by fluid changes in trans-thoracic tissues and the lung to assist in the detection and quantification of pulmonary edema and thus pulmonary congestion (see Column 12, lines 31-37). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and methods of Prutchi with a step of measuring impedance that are caused by fluid changes and relating it to fluid changes in the lung, as taught by Pitts-Crick et al, to assist in the detection and quantification of pulmonary edema and thus pulmonary congestion.

Regarding claims 3 and 24, the implantable cardiac device of Prutchi that applies a voltage between the first and second internal electrodes to accomplish the current injection (see Columns 7-8, lines 16-50).

Regarding claims 4 and 25, the housing of Prutchi can serve as the second internal electrode (see Column 7, lines 16-30).

Regarding claim 7, see the rejection of claim 3 above.

Regarding claims 8, 10, 30, and 31, Prutchi discloses the claimed invention except for the implantable device being an implantable cardioverter defibrillator. Pitts-Crick et al teaches it is known to provide an ICD and any other medical device capable of stimulating cardiac tissue to an impedance monitoring system because it is known to provide a variety of substitutions of implantable devices for delivering electrical stimuli to cardiac tissue (see Column 3, lines 54-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Prutchi to include either an implantable cardioverter defibrillator or implantable cardiac resynchronization therapy device, as taught by Pitts-Crick et al, because it is known to provide a variety of substitutions of implantable devices for delivering electrical stimuli to cardiac tissue.

Regarding claim 9, see Column 6, lines 55-63.

Regarding claim 11, see Column 7, lines 22-26, wherein the sensing circuits measure lead impedance of the first and second internal electrodes.

Regarding claim 12, the device of Prutchi is capable of telemetering a voltage and impedance (see Column 7, lines 9-15).

Regarding claims 14 and 36, Prutchi teaches it is known to pass electrical currents between a second and third electrode (see Column 7, lines 16-30), wherein the third electrode is electrode 27 and the second electrode is element 60 and measuring a voltage between a third electrode attached to the upper right shoulder region and another of the external electrodes (element 108C in Figure 3).

Regarding the positioning of the external electrodes in claim 36, Prutchi teaches it is known to provide thoracic impedance electrodes at different locations on the body (see Column 9, lines 61-67), and goes on to suggest places for the electrodes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place external electrodes, on the suprasternal notch region and medially over the ribs, to provide maximum coverage of electrical monitoring for assessing the degree of pulmonary congestion.

Regarding claims 15 and 37, the third electrode of Prutchi is positioned in atrium of the heart, so it could be either right or left side (see Column 7, line 17).

Regarding claims 16, 17, 18, 38 and 39, Prutchi discloses the claimed method except for calculating a second impedance by taking the ratio of the second measured voltage and the second injected current and computing an average (or multiple

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averages) of the calculated impedances. Pitts-Crick et al teach it is known to measure multiple trans-thoracic impedance values based on different excitation currents so that the changes can be monitored and an accurate determination of fluid present in the lungs can be determined (see Column 15, lines 1-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Prutchi with a step of calculating a second impedance by taking the ratio of the second measured voltage and the second injected current and computing an average of the calculated impedances, as taught by Pitts-Crick et al, to measure multiple trans-thoracic impedance values based on different excitation currents so that the changes can be monitored and an accurate determination of fluid present in the lungs can be determined.

Regarding claim 19, see Column 7, lines 9-15, and this data includes injected current.

Regarding claims 20, 21, 42, and 43, Prutchi discloses the claimed invention except for comparing a number of calculated impedances to detect a change in volume of fluid in the lung, and detecting changes in pulmonary edema. Pitts-Crick et al teaches it is known to compare a number of calculated impedances to detect a change in the volume of fluid in the lung and to detect changes in pulmonary edema to determine the degree of pulmonary congestion and to monitor the patient and degree of congestion during everyday activities (see Columns 15-17, lines 1-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method of Prutchi with a step of comparing a number of calculated

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impedances to detect a change in volume of fluid in the lung, and detecting changes in pulmonary edema, as taught by Pitts-Crick et al, to determine the degree of pulmonary congestion and to monitor the patient and degree of congestion during everyday activities.

Regarding claim 40, the device of Prutchi as modified is capable of comparing two weighted averages to detect changes in pulmonary edema.

Claims 5, 6, 26, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Pitts-Crick et al as applied to claims 4 and 25 above, and further in view of Erlebacher (6473640). Prutchi as modified discloses the claimed invention except for the second electrode being located near the upper portion of the left lung. Erlebacher teaches it is known to provide an electrode over an upper portion of the left lung (see Figure 2 around element 15, and Column 6, lines 13-67), to accurately determine the congestion of the lung. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device of Prutchi with the second electrode being located near the upper portion of the left lung, as taught by Erlebacher, to accurately determine the congestion of the lung.

Regarding the positioning of the external electrodes in claims 6 and 27, Prutchi teaches it is known to provide thoracic impedance electrodes at different locations on the body (see Column 9, lines 61-67), and goes on to suggest places for the electrodes, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place external electrodes, on the anterior left shoulder and over

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the central dorsal region, to provide maximum coverage of electrical monitoring for assessing the degree of pulmonary congestion.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Application Number 2004/0116819 Alt discloses a congestive heart failure monitor and ventilation measuring implant

U.S. Pat. No. 5,755,742 Schuelke et al disclose a cardioversion/defibrillation lead impedance measurement system

U.S. Pat. No. 6,104,949 Pitts-Crick et al disclose a medical device.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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